Better After CHoosing

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23900

Bron
NTR

Verkorte titel
BACH

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: investigator initiated trial by Rheumatology Research Center Northern Netherlands
Overige ondersteuning: Investigator initiated research with a grant from Galapagos

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Group I
- The proportion of subjects choosing filgotinib at baseline.

Total study population, Group I versus Group II:
- Treatment satisfaction at week 24 on a 5-point Likert scale for current medical treatment ranging from 1: very dissatisfied, 2: dissatisfied, 3: neither dissatisfied nor satisfied, 4: satisfied, 5: very satisfied.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Despite their efficacy in the treatment of Rheumatoid Arthritis and their partial advantage over traditional bDMARDs, JAK inhibitors (JAKi or tsDMARDs) have not gained preference over Tumor Necrosis Factor inhibitors (TNFi) in guidelines or clinical practice. The biggest influence on recent guidelines has been the “Treat To Target” principle (T2T), in which Shared Decision Making (SDM) plays a key part. Patient preference has proven to be a large barrier in treatment adjustments (14- 37%) 1,2,3 while patients showed better adherence and higher treatment satisfaction when engaged in Shared Decision Making.4 From survey studies it is suggested that patient preference and satisfaction will be in favour of oral JAK inhibitors over parenteral biologics. 5,6,7 We want to establish the treatment preference of patients with active RA and compare the treatment satisfaction of patients who are given the opportunity to choose between the JAKi filgotinib and TNFi, to the treatment satisfaction of patients who are randomized to the same treatment options.
In addition to higher treatment satisfaction and better adherence, we expect to find an improvement in DAS28-, HAQ-, SQUASH- and WPAI-scores and also an improved activity and work productivity.
Objective: To evaluate the actual preference of patients when they decide themselves which mode of action they want to use for treatment of rheumatoid arthritis.
To evaluate differences in treatment satisfaction between patients who can choose their therapy and those patients that are randomized for the same treatment options.
To evaluate if adherence to therapy is increased when patients decide their own therapy.
To evaluate the difference in improvement of disease activity by the Disease Activity Score (DAS28) and physical activity as measured by SQUASH questionnaire and fitness trackers.
Study design: This study is a multicenter, randomized, 24-week, open label trial
Study population and intervention: Early, bDMARD naive RA patients, of whom a group of 50 patients will be given the opportunity to choose between either TNFi (etanercept 50 mg SC once a week or adalimumab 40 mg SC once every two weeks) or filgotinib, an oral JAKi, 200 mg once a day while another group of 50 patients will be randomized to the same treatment arms.
Main study parameters/endpoints: The two primary endpoints consist of:
-The proportion of subjects in the first subgroup choosing filgotinib therapy at baseline
-Treatment satisfaction of both subgroups at week 24 at a 5-point Likert scale for current medical treatment.
Burden and risks associated with participation, benefit and group relatedness: All medication is prescribed at the indicated dosages used in clinical care, according to international guidelines. Study burden and risks are similar to daily clinical care: In addition to daily clinical

care only one half of the participants has to make the treatment choice and all participants will fill in questionnaires, which will take about 15 minutes to complete.

Doel van het onderzoek

From survey studies it is suggested that patient preference and satisfaction will be in favour of oral JAK inhibitors over parenteral biologics. 5,6,7 We want to establish the treatment preference of patients with active RA and compare the treatment satisfaction of patients who are given the opportunity to choose between the JAKi filgotinib and TNFi, to the treatment satisfaction of patients who are randomized to the same treatment options.
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Onderzoeksopzet

Primary timepoints:
Group I
- Baseline: The proportion of subjects choosing filgotinib at baseline (percentage and proportion).

Total study population, Group I versus Group II:
- Week 24: Treatment satisfaction at week 24 on a 5-point Likert scale for current medical treatment ranging from 1: very dissatisfied, 2: dissatisfied, 3: neither dissatisfied nor satisfied, 4: satisfied, 5: very satisfied.

Secondary timepoints:
Group I
- Week 6 and 24: How patients rate being informed by the neutral information video on a Likert scale of agreement on being well informed.
- Week 6 and 24: How do patients in the treatment Choice group I rate being in control for their treatment decision: by questionnaire (with 5 point Likert Scales for agreement on being well informed, treatment satisfaction,enjoying to have had the medication-choice and enjoying to be involved in their treatment choice and the choice being easy)
- Week 24: Proportion of subjects who would choose filgotinib (again or otherwise) if they were allowed to choose again;
- week 0: Proportion of patients who were not able to make a treatment decision.

Total study population:
- Week 0, 6, 12, 18 and 24: Adherence measurement by 5-item Self-Reported Medication Adherence Report Scale (MARS-5).
- Week 6, 12 and 24: Change from Baseline of Disease Activity Score (DAS28) and physical activity as measured by SQUASH questionnaire and fitness tracker (daily footsteps, speed of acceleration, mean heart beat)
- Week 6, 12, 18, 24: Time to remission by both PROMs and DAS28 (with remission defined as DAS28 <2.6) in days.
And a comparison of percentage of remission for Group I JAKi- and TNFi-, Group II JAKi- and

TNFi-subgroups
- Week 12 and 24: Change from baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) HAQ-DI Scores from 0-3 with 25 possible values (i.e., 0, 0.125, 0.250, 0.375 … 3).
- Week 6, 12, and 24: Change from baseline in Work Productivity and Activity Impairment (WPAI) Score: range 0–100% greater scores indicate greater impact of health.
- Week 0, 6, 12, 18 and 24: Registration of concomitant medication use (NSAIDs, analgesics, other DMARDs, i.a. and i.m. corticosteroid injections).
- Weekly number of footsteps and improvement of DAS28 at the next visit. measured by activity tracker and DAS 28 score
- Week 0: Actual preference of the treating rheumatologists when they decide which mode of action for treatment of each of their patients they would have chosen: Percentages of either filgotinib or TNFi.
- Week 0, 6 and 24 (patient): To evaluate which factors contribute to a difference in treatment choice between patient and rheumatologist (questionnaire: mode of administration, comorbidity, side effects, patient-peer information)

Onderzoeksproduct en/of interventie

BACH is an open label trial where a total of 100 patients who meet the eligibility criteria and agree to participate will be randomized 1:1 into two groups of 50 patients:
- Group I: The “Choice Group”: N=50
- Group II: The “Randomization Group”: N=50
Patients in Group I will be allowed to choose between TNFi (preferred specialty of each site) and filgotinib. Patients in group B will be randomized in a ratio of 1:1 to those same treatment options (filgotinib or TNFi).

Apart from the Choice versus Randomization aspect of the study, groups I and II have the same visit schedule and activities. All patients will receive regular and proven effective treatment.
The subjects in Group I will be informed by a standardized, neutral information video.
At each visit a DAS28 disease severity score and blood withdrawal will be performed as in regular daily care and the questionnaires/ PRO’s will be filled in.

Physical activity will be measured with a fitness tracker wristband which will be provided to the patients and data will be obtained through an anonymized account for use of which patients give permission on the ICF.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Demographic and general characteristics:
- Adult male or female patients, at least 18 years of age.
- Able and willing to give written informed consent.
- Have sufficient knowledge of the Dutch language to be able to comply with the requirements of the study protocol.

Inclusion criteria:
- Diagnosis of adult-onset RA as defined by the 2010 ACR/ EULAR Rheumatoid arthritis classification criteria;
- Diagnosis of RA for ≥ three months;
- Are being treated ≥ three months with ≥ 1 csDMARD therapy;
- Have had an inadequate response or intolerance to at least 1 csDMARD;
- Have moderately to severely active RA to the discretion of the rheumatologist or defined as a DAS28 ≥ 3.2 at screening and baseline visits;
- Subjects must have been on a stable dose of csDMARD therapy (restricted to methotrexate, chloroquine, hydroxychloroquine, sulfasalazine, or leflunomide) for ≥ 4 weeks prior to the baseline visit.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous treatment with any biological DMARD or targeted synthetic DMARD/JAKi;
- Inflammatory rheumatic disease other than RA, except for secondary Sjögren’s syndrome.
- Having a contraindication for either TNFi or filgotinib;
- Latent or active tuberculosis;
- Active or recurrent infections;
- History of any malignancy within 5 years except for successfully treated NMSC or localized carcinoma in situ of the cervix;

- ≥ 3x upper limit of normal ALT, AST;
- eGFR ≤ 30 ml/min;
- planned or actual pregnancy or planning to father a child.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
NA

Ethische beoordeling

Positief advies

Datum:	10-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9439
Ander register	RTPO Leeuwarden (METC) : COV 202100003

Resultaten

Samenvatting resultaten
Not yet